

APPLICATION FOR UNITED STATES LETTERS
PATENT

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**INSULATED IMPLANTABLE ELECTRICAL
CIRCUIT**

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FEDERALLY SPONSORED RESEARCH

This invention was made with government support under grant No. R24EY12893-01, awarded by the National Institutes of Health. The government has certain rights in the invention.

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PRIORITY CLAIM

This application claims the benefit of U.S. Application Number 60/402591 filed on August 9, 2002.

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FIELD OF THE INVENTION

This invention relates to implantable medical devices, especially implantable cables and electrode arrays for stimulation, recording and interconnection.

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BACKGROUND OF THE INVENTION

Arrays of electrodes for neural stimulation are commonly used for a variety of purposes. Some examples include U.S. Patent No. 3,699,970 to Brindley, which describes an array of cortical electrodes for visual stimulation. Each electrode is attached to a separate inductive coil for signal and power. U.S. Patent No. 4,573,481 to Bullara describes a helical electrode to be wrapped around an individual nerve fiber. U.S. Patent No. 4,837,049 to Byers describes spike electrodes for neural stimulation. Each spike electrode pierces neural tissue for better electrical contact. U.S. Patent No. 5,215,088 to Norman describes an array of spike electrodes for cortical stimulation. U.S. Patent No. 5,109,844 to de Juan describes a flat electrode array placed against the retina for visual stimulation. U.S. Patent 5,935,155 to Humayun describes a retinal prosthesis for use with a flat retinal array.

Packaging of a biomedical device intended for implantation in the eye, and more specifically for physical contact with the retina, presents a unique interconnection challenge. The consistency of the retina is comparable to that of wet tissue paper and the biological media inside the eye is a corrosive saline 5 liquid environment.

Thus, the device to be placed against the retina, in addition to being comprised of biocompatible, electrochemically stable materials, must appropriately conform to the curvature of the eye, being sufficiently flexible and gentle in contact with the retina to avoid tissue damage, as discussed by 10 Schneider, *et al.* [see A. Schneider, T. Stieglitz, W. Haberer, H. Beutel, and J.-Uwe Meyer, "Flexible Interconnects for Biomedical Microsystems Assembly," IMAPS Conference, January 31, 2001.] It is also desirable that this device, an electrode array, provides a maximum density of stimulation electrodes. A 15 commonly accepted design for an electrode array is a very thin, flexible circuit cable. It is possible to fabricate a suitable electrode array using discrete wires, but with this approach, a high number of stimulation electrodes cannot be achieved without sacrificing cable flexibility (to a maximum of about 16 electrodes).

Known insulators for implanted electrical circuits include polyimide and 20 silicone dielectrics. They have limited lives once implanted. The polyimide slowly degrades upon exposure to the living tissue and allows water to reach the electrical conductor, eventually leading to at least partial electric current leakage.

Known techniques for implanted electrical circuits do not result in a hermetic package that is suitable for chronic implantation in living tissue. 25 Therefore, it is desired to have an insulated electrical conductor that ensures that the electronic package will function for long-term implant applications in living tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

30 FIG. 1 illustrates a cross-sectional view of an implantable electrical circuit.

FIG. 2 illustrates a cross-sectional view of an alternate implantable electrical circuit.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The preferred embodiment is an implantable insulated electrical circuit for electrical transmission within living organisms. These assemblies provide electrical conduction, isolation of the electrical conductors from the environment in the living tissue and from each other, and mechanical support for the electrical conductor. Electrical device assemblies that are commonly used for stimulation and or recording within the body benefit from the invention. Neural stimulators or sensors are of particular interest, including retinal electrode arrays. The implantable insulated electrical conductors may also be used to connect discrete components of an implanted medical device, permitting the transmission of electrical signals, power, as well as providing mechanical connection. Key attributes include good electrical insulation properties, low moisture absorption, appropriate mechanical characteristics and ease of fabrication.

Polyparaxylylene is a known polymer that has excellent implant characteristics. One example, Parylene, manufactured by Specialty Coating Systems (SCS), a division of Cookson Electronic Equipment Group, located in Indianapolis, Indiana, is a preferred material. Parylene is available in various forms, such as Parylene C, Parylene D, and Parylene N, each having different properties. The preferred form is Parylene C, although it is recognized that many forms of polyparaxylylene may exist or may be developed that are suitable for this application.

The use of Parylene was mentioned, but not pursued, by Sonn and Feist. [see M. Sonn and W. M. Feist, "A Prototype Flexible Microelectrode Array for Implant-Prosthesis Applications," Medical and Biological Engineering, 778-791, November 1974.] Stieglitz, et al. published fabrication details of similar items manufactured using polyimide. [see T. Stieglitz, H. Beutel, M. Schuettler, and J.-U. Meyer, "Micromachined, Polyimide-Based Devices for Flexible Neural Interfaces," Biomedical Microdevices, 2:4, 283-294, 2000.] Ganesh wrote a thesis on ribbon cables for neural recording and stimulation using polyimide [see B. Ganesh, "A Polyimide Ribbon Cable for Neural Recording and Stimulation Systems," Thesis, University of Utah, March 1998.] Parylene is widely used as

an electrical insulating and barrier material in commercial electronic devices. It is well known to use Parylene as a conformal coating on printed circuit boards. While discrete wires have been coated with Parylene for implantation, such as with cochlear implants, the application of Parylene as an electrical insulator for 5 implantable electrical circuits, as embodied by this invention, is unknown to the inventors.

The moisture vapor transmission rates compare favorably with those of other conformal coating materials. The rate for Parylene C is superior to almost all polymeric materials. The Parylenes resist room temperature chemical attack 10 and are insoluble in organic solvents up to 150°C. Parylene C can be dissolved in chloro-naphthalene at 175°C, and Parylene N is soluble at the solvent's boiling point (265°C). The thermal properties are given in **Table 1** and the electrical properties are given in **Table 2**.

TABLE 1. Parylene Thermal Properties (2)

Properties	Method	Parylene N	Parylene C	Parylene D	Epoxides (1)	Silicones (1)	Urethanes (1)
Melting Point (°C)	1	420	290	380	cured	cured	~170
T5 Point (°C) (modulus = $(10^5$ psi)	1	160	125	125	110	~125	~30
T4 Point (°C) (modulus = $(10^4$ psi)	1	>300	240	240	120	~80	0
Linear Coefficient of Expansion at 25°C ($\times 10^5$, $(^{\circ}\text{C})^{-1}$)	-	6.9	3.5	3-8	4.5-6.5	25-30	10-20
Thermal Conductivity at 25°C (10^{-4} cal/(cm \cdot s \cdot °C))	2	3.0	2.0	-	4-5	3.5-7.5	5.0
Specific Heat at 20°C (cal/g °C)	-	0.20	0.17	-	0.25	-	0.42

Test Methods 1. Taken from Secant modulus-temperature curve
2. ASTM C 177

5 (1)Properties and methods as reported in *Modern Plastics Encyclopedia*, issue for 1968, Vol. 45/No. 1A, McGraw Hill, New York, 1967
(2) After Specialty Coating Systems, Indianapolis, IN.

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TABLE 2. Parylene Electrical Properties (3)

Properties (1)	Parylene N	Parylene C	Parylene D	Epoxides (2)	Silicones (2)	Urethanes (2)
Dielectric Strength, dc volts/mil short time, 1 mil films ^a	7,000	5,600	5.500			
Corrected to 1/8 inch	630	500	490	400-500	550	450-500
Volume Resistivity ohm-cm, 23°C, 50% RH ^b	1.4×10^{17}	8.8×10^{16}	1.2×10^{17}	10^{12} - 10^{17}	10^{15}	10^{11} - 10^{15}
Surface Resistivity, ohms, 23°C, 50% RH ^b	10^{13}	10^{14}	10^{16}	10^{13}	10^{13}	10^{14}
Dielectric Constant ^c						
60 Hz	2.65	3.15	2.84	3.5-5.0	2.7-3.1	5.3-7.8
1 KHz	2.65	3.10	2.82	3.5-4.5	2.6-2.7	5.4-7.6
1 MHz	2.65	2.95	2.80	3.3-4.0	2.6-2.7	4.2-5.2
Dissipation Factor						
60 Hz	0.0002	0.020	0.004	0.002-0.01	0.001-0.007	0.015-0.05
1 KHz	0.0002	0.019	0.003	0.002-0.02	0.001-0.005	0.04-0.06
1 MHz	0.0006	0.013	0.002	0.03-0.05	0.001-0.002	0.05-0.07

^a ASTM D 149

^b ASTM D 257, 1 in² mercury electrodes

^c ASTM D 150, 1 in²

15 (1) Properties measured on Parylene films, 0.001 in thick.
(2) Properties and methods as reported in *Modern Plastics Encyclopedia*, issue for 1968, vol. 45, No. 1A, McGraw Hill, NY, 1967.
(3) After Specialty Coating Systems, Indianapolis, IN.

A cross-sectional view of a preferred embodiment of the invention is presented in **FIG. 1**. An electrical circuit 1 is shown generally being formed on a rigid substrate 2. The substrate 2 may be selected from glass or ceramic, such as alumina or silicon. Substrate 2 is preferably comprised of glass.

5 A first Parylene layer 4 is deposited on the substrate 2 from a vapor phase that is produced by known techniques, such as thermal decomposition. It is known that Parylene is the polymer "polyparaxylylene" and that any source of this material may be used to implement this invention. The inventors use the term Parylene, as is common in industry practice, to indicate the class of 10 polyparaxylylene polymers.

An electrical conductor 6 is deposited by a known physical vapor deposition method, such as sputtering or evaporation. While the preferred embodiment is to an electrical conductor 6 that is comprised of one material, it is clear that the electrical conductor 6 may also be comprised of layers of several 15 materials. Alternatively, the conductor 6 or combination thereof may be deposited by other known methods, such as direct write, plating, or electrophoresis. The electrical conductor 6 is patterned by known techniques, such as lift-off or etching. The electrical conductor 6 may be comprised of a single metal or in an alternate embodiment, from several metals that may be 20 layered or alloyed, that are selected from a group of electrically conductive biocompatible materials having favorable electrochemical characteristics, such as titanium, platinum, gold, iridium, and their alloys. Multiple metals may be used in order to achieve desired characteristics. For example, adhesion and barrier 25 layers are commonly used in electronics where individual metal layers are combined to yield a more functional circuit stack. These electrical conduction paths, traces, bond pads, and electrode sites are formed prior to depositing a second layer of Parylene 8 to the device. Typical thicknesses of each Parylene layer are in the range of 0.5 to 50 microns, and preferably are about 3 to 15 microns thick. An alternate embodiment uses metals that are not biocompatible, 30 so long as they are completely encapsulated by the surrounding structural elements and thus do not contact living tissue.

In an alternate embodiment, non-biocompatible materials, such as chrome, silver, or copper may be used as the electrical conductor 6. The electrical conductor 6 is then coated with a biocompatible, hermetic coating in the exposed aperture 6 area. This coating is preferably titanium nitride, although in 5 alternative embodiments it may be an electrically conductive biocompatible metal, such as titanium, platinum, gold, iridium, or their alloys. The Parylene layers cover and protect the rest of the electrical conductor 6.

Apertures 10 are patterned by known techniques, such as by dry etching or laser ablation, or by reactive ion etching. The apertures 10 permit electrical 10 conduction to either tissue or a connected implanted device. The apertures 10 define an electrode area on the electrical conductor 6.

The rigid substrate 2 is removed by known techniques, such as mechanical separation or etching, where mechanical separation is the preferred technique.

15 As a further embodiment of the invention, adhesion between the first layer of Parylene 4 and the second layer of Parylene 8 is preferably improved by one or more of the following techniques:

- (a) Silane application between Parylene layers.
- (b) Chemical modification of the Parylene surface to create an energetic, a reactive, or an amorphous surface (Parylene is amorphous as deposited).
- 20 (c) Roughening of the Parylene surface.
- (d) Thermal compression of the Parylene layers.

Techniques (b) and (c) can be used to improve the metal to Parylene adhesion, if applied prior to metal deposition.

25 More than one electrical conductor 6 may be deposited adjacent to the Parylene. Additional metal layers may be deposited that are protected by additional Parylene layers, such that a multilayered higher density electrical circuit is achieved.

A further alternative embodiment, FIG. 2, of the invention preferably 30 replaces the first layer of Parylene 4 with a polymer layer 111, which is preferably polyimide, such that beginning with the rigid substrate 102, the layers

are, preferably, polymer layer 111 (polyimide) - electrical conductor 106 - layer of Parylene 104. The polyimide is preferably applied as a liquid.

In an alternative embodiment, not illustrated, one applies a first polymer coating, preferably polyimide, prior to depositing the first Parylene layer, such 5 that beginning with the rigid substrate, the layers are, polymer layer (preferably polyimide) - first Parylene layer - electrical conductor - second layer of Parylene.

In yet another embodiment, not illustrated, a polymer coating, preferably of polyimide is applied between the Parylene layer and the electrical conductor.

10 In further embodiments, not illustrated, a polymer coating, preferably of polyimide is deposited on either side of the second layer of Parylene, either in the presence or absence of a polymer coating on the first layer of Parylene.

15 Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.